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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,649	05/23/2001	Julian M.C. Golec	VPI/00-114	1044

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VERTEX PHARMACEUTICALS INC.
130 WAVERLY STREET
CAMBRIDGE, MA 02139-4242

EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Appli ation No.	Appli ant(s)	
	09/863,649	GOLEC, JULIAN M.C.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-8 and 12-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3,5-7,18-29 and 31-42 is/are allowed.
- 6) ☒ Claim(s) 8,12-17,30 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on December 3, 2004 has been entered.

It should be noted that Applicants' amendment filed December 3, 2004 was in improper format under 37 CFR 1.121. Because the amendment after final rejection filed May 5, 2004 was entered, the amendments contained therein should not have been repeated in the amendment filed December 3, 2004. Also, because claim 12 is designated as "Previously Presented", the underlining mark at claim 12, page 10, line 16, is improper.

The examiner telephoned Applicants' attorney on December 21, 2004 to enquire as to the status of a further preliminary amendment. However, the telephone call was not returned by the time it became necessary to prepare this Office action.

2. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to the "provided that..." clause in claim 43, it is not clear if "the heterocyclic group" refers only to the optionally substituted heterocyclic group of line 3, or if it also refers to the heterocyclic group in the optionally substituted heterocyclylalkyl group of line 4.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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4. Claims 8, 12, 16, 17, 30, and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Ohmoto et al (U.S. Patent No. 6,136,834). Ohmoto et al teach compounds in Examples 18(23), 18(24), 19(21), and 19(22) which meet the requirements of Applicant's formula I in which R¹ is R which is a substituted heterocyclalkyl group. The compounds of Ohmoto et al are ICE inhibitors which are used to treat diseases such as infectious diseases, Alzheimer's disease, AIDS, leukemia, and neoplasm. See, e.g., column 219, line 10 - column 220, line 59; column 414, line 37 - column 415, line 21; column 422, line 42 - column 423, line 26; and claims 13-14. These compounds of Ohmoto et al are also deemed to constitute pharmaceutically acceptable derivatives of the other compounds embraced by Applicant's formula I in view of their structural and functional similarity. With respect to instant claim 43, this rejection assumes that the "provided that" clause refers only to the heterocyclic group of line 3 of the claim and does not limit the optionally substituted heterocyclalkyl group of line 4. See also the above rejection under 35 U.S.C. 112, second paragraph.

5. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being obvious over Ohmoto et al (U.S. Patent No. 6,136,834) as applied against claims 8, 12, 16, 17, 30, and 43 above, and further in view of Hagmann et al (U.S. Patent No. 5,866,545) and Baust et al (U.S. Patent No. 6,045,990). Ohmoto et al do not teach using their ICE inhibitors to treat complications associated with coronary artery bypass grafts, or to preserve cells, organs to be transplanted, or blood products. Hagmann et al disclose the use of ICE inhibitors to treat graft rejection and graft-versus-host disease (see, e.g., column 2, lines 38-54). Baust et al disclose the use of caspase protease inhibitors to treat animal or human organs, tissues or cells for hypothermic storage, e.g., prior to transplantation (see, e.g., column 5, lines 58-61; column 16, lines 36-54;

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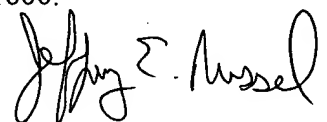
and claim 6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to use the ICE inhibitors of Ohmoto et al to treat complications associated with coronary artery bypass grafts, or to preserve cells, organs to be transplanted, or blood products, because Hagmann et al and Baust et al teach that these are known uses for ICE inhibitors; because the ICE inhibitors of Ohmoto et al are structurally and functionally analogous to those described by Hagmann et al and Baust et al; because it is the ability to inhibit ICE, rather than the presence of any particular chemical structure, which would have been expected to be necessary in order to treat graft rejection and graft-versus-host disease as taught by Hagmann et al or to treat animal or human organs, tissues or cells for hypothermic storage as taught by Baust et al; and because it is prima facie obvious to use ICE inhibitors or caspase inhibitors for the same pharmaceutical purposes that other ICE inhibitors and caspase inhibitors are used.

6. The examiner maintains his position for the reasons of record.

7. Claims 1-3, 5-7, 18-29, and 31-42 are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
January 5, 2005